

REMARKS

This application contains Claims 1-31, the status of which is as follows:

- (a) Claims 7-9, 16, 18-20, and 25-27 have been cancelled without prejudice.
- (b) Claim 1 has been currently amended.
- (c) Claims 2-6, 12-15, 17, and 24 are as originally filed.
- (d) Claims 10, 11, and 21-23 are previously presented.
- (e) Claims 28-31 are new.

No new matter has been added. Reconsideration is respectfully requested.

Amendments to the specification

The Examiner required that the first paragraph of the specification be amended to refer to the serial number of U.S. Patent 6,725,093. This amendment has been made. The first paragraph has also been amended to reflect the priority claims of PCT Patent Application PCT/IL99/00594.

Drawings

The Examiner objected to the drawings because of an informality. Corrected drawings are enclosed herewith.

Claim amendments and changes of status:

Claim 1 of the present patent application has been currently amended to be identical to Claim 1 of the parent application as originally filed (U.S. Patent Application S.N. 09/831,100, hereinafter "the parent application").

Claims 2-6, 12-15, 17, and 24 are marked "original." These claims had been cancelled in the preliminary amendment filed March 10, 2004, in the present patent application.

Claims 10, 11, and 21-23 are marked as "previously presented," because they had been amended to remove multiple dependencies upon entry to the national phase of the parent application.

Method Claims 28 and 29 and apparatus Claims 30 and 31 are new. Claims 28 and 30 recite assessing heart rate variability of the patient, and Claims 29 and 31 recite increasing the intensity of the ETC signals as an inverse function of the heart rate variability. These new claims are supported at least in the publication of the present patent application (U.S. Patent Application Publication 2004/0215267) in paragraph [0053], as follows:

[0053] Heart rate variation may also, in itself, be used as an indicator for controlling the intensity of ETC stimulation. It is known in the art that while the body is at rest, the heart rate tends to have a high degree of variability, i.e., there are relatively large changes in the instantaneous heart rate from beat to beat. On the other hand, during exertion, when the heart is under stress, the heart rate becomes nearly constant. Thus, in a preferred embodiment of the present invention not shown in the figures, the ETC duty cycle is adjusted so as to provide ETC intensity that increases as an inverse function of heart rate variability.

#### Statutory Double Patenting

Claim 1 of the present patent application was rejected for claiming the same invention as Claim 1 of U.S. Patent No. 6,725,093. Claim 1 as currently amended does not claim the same invention as Claim 1 of the '093 patent, so the Applicants respectfully submit that this rejection is now moot.

Novelty

The Examiner cited three documents, namely, Bornzin et al. (U.S. Patent No. 5,514,162), Nappholz (U.S. Patent No. 5,792,198), and Darvish et al. (PCT Publication No. WO 00/04947) against Claims 1 and 12 in the parent application, as well as against some dependent claims of these independent claims. Since allowable subject matter was identified in some of the claims that were pending in that application, the Applicants chose to amend the claims in order to have a patent issue on the identified allowable subject matter as soon as possible.

Claims 1 and 12 as filed in the parent application are currently pending in the present patent application. The Applicants respectfully submit that the following arguments show that Claims 1 and 12 as currently pending (and as rejected in the parent application) recite patentable subject matter.

The Examiner cited Darvish et al. under Section 102(e) against Claims 1 and 12. Darvish et al. was filed on July 18, 1999, claiming the priority of an Israeli patent application. The present application enjoys the benefit of Israel Patent Application No. 127,092, which was filed on November 16, 1998, prior to the "102(e) date" of the Darvish et al. reference. This priority document discloses in its entirety the present invention as claimed. Therefore, the Applicants respectfully submit that the rejection over Darvish et al. should be withdrawn.

Bornzin et al. and Nappholz disclose rate responsive pacemakers (or a system and method for determining the slope of a transfer function for such a pacemaker). A pacemaker is a device that generates a pacing pulse, thus controlling the patient's heart rate (see, for example, Bornzin et al. in lines 60-63 of Column 1). Pacemakers normally utilize a pacing pulse generator for generating pacing pulses such as that disclosed in Nappholz (Column 2, lines 42-43).

A pacing pulse is an excitatory electric pulse that induces activation potentials in cardiac muscle cells. Both independent claims of the present invention (Claims 1 and 12) recite excitable tissue control (ETC) stimulation. This ETC is defined in the present application (paragraph [0004]) as follows:

The non-excitatory field is such as does not induce activation potentials in cardiac muscle cells, but rather modifies the cells' response to subsequent activation. In the context of the present patent application, the use of such a non-excitatory field is referred to as Excitable Tissue Control (ETC).  
[emphasis added]

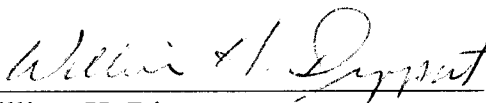
ETC was neither disclosed nor suggested in Bornzin et al. or in Nappholz. Thus, at least for this reason, the present invention as currently claimed is novel in view of both Bornzin et al. and in Nappholz.

In addition, whilst Bornzin et al. and Nappholz describe pacing of the heart, Claims 1 and 12 recite enhancing contractility of the heart. Contractility enhancement is inherently different from pacing. For at least this reason the present invention as claimed is also inventive in view of both Bornzin et al. and Nappholz.

Applicants believe the amendments and remarks presented hereinabove to be fully responsive to all of the grounds of rejection on objection raised by the Examiner. In view of these amendments and remarks, Applicants respectfully submit that all of the claims in the present application are now in order for allowance. Notice to this effect is respectfully requested.

Respectfully submitted,

May 9, 2006

  
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